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A Cost-Effectiveness Analysis Comparing a Conventional Mechanical Needle to a Radiofrequency Device for Transseptal Punctures

INTRODUCTION

- Previous studies have demonstrated that use of a dedicated radiofrequency (RF) transseptal puncture (TSP) device (**NRG™** Transseptal Needle, Baylis Medical*) is associated with reductions in transseptal complications, failures to cross the septum, and transseptal access time, as compared to use of a mechanical transseptal needle (BRK™, Abbott).
- While the upfront cost of the RF TSP device is more than the mechanical needle, the cost-effectiveness of the two options has not previously been evaluated.

METHODS

- A decision tree was prepared to evaluate the cost-effectiveness of the RF TSP device and the mechanical needle, as used during pulmonary vein isolation (PVI) procedures, in three different clinical scenarios: single TSP with one device (base case), double TSP with one device, and double TSP with two devices.
- Probability and clinical cost inputs were located in peer-reviewed literature and healthcare databases, while costs of TSP materials were obtained from the University of California, San Francisco electrophysiology lab.
- The total cost at 30 days was the sum of PVI procedure costs and costs of TSP-related complications.
- Effectiveness was defined as probability of survival at day 30 following TSP success.
- Incremental cost-effectiveness ratios (ICER) were calculated for these four scenarios.
- One-way and Monte-Carlo probabilistic sensitivity analyses were then performed, with the latter used to prepare a cost-effectiveness acceptability curve (CEAC).

RESULTS

- The cost-effectiveness rankings of the four scenarios are shown in Table 1.
- In all scenarios the RF TSP device was found to be dominant, as compared to the mechanical needle.
- The probabilistic sensitivity analysis and CEAC found that the RF TSP device was more cost-effective at any willingness-to-pay threshold.

DISCUSSION AND CONCLUSIONS

- When all costs are accounted for, the RF TSP device is less costly and more effective than the mechanical needle, despite a greater upfront equipment cost.
- The modified base case analysis suggested that the shorter time-to-transseptal with the RF TSP device may further increase cost savings, which may enable faster lab turn-over and more efficient use of personnel and space.
- It is noted that variations in procedural and equipment costs between centers could influence the level of dominance or cost-effectiveness reported.

Table 1. Cost-Effectiveness of RF TSP device compared to mechanical needle

Scenario	Incremental Total Cost at 30 Days for RF TSP device ($)†	Incremental Effectiveness at 30 Days for RF TSP Device (%)†	ICER‡
Single TSP with 1 device (base case)	-41	+0.9	Dominant
Double TSP with 1 device	-338	+1.1	Dominant
Double TSP with 2 devices	-158	+1.1	Dominant
Single TSP with 1 device (modified base case, with PVI costs adjusted for transseptal time savings)	-774	+0.9	Dominant

* A wholly-owned subsidiary of Boston Scientific Corporation.
† As compared to mechanical transseptal needle
‡ The term "Dominant" indicates a device was associated with higher effectiveness and lower cost TSP denotes transseptal puncture; RF, radiofrequency; ICER, incremental cost-effectiveness ratio; PVI, pulmonary vein isolation

NRG™ Transseptal Needle

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. • Do not alter this device in any way. • The NRG Transseptal Needle is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • For RFP-100: Do not attempt to puncture with an initial power setting of greater than 10 Watts. The initial attempt should be made with a setting of 10 Watts. In subsequent punctures, the power setting can be increased, if necessary. • The pressure transducer system used with the NRG Transseptal Needle must comply with the electrical safety requirements of IEC 60601. Failure to use compliant pressure transducers may result in patient or operator injury.

PRECAUTIONS: • Do not attempt to use the NRG Transseptal Needle or ancillary equipment before thoroughly reading the accompanying Instructions for Use. • Radiofrequency puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised. • Visually inspect the needle prior to use. Do not use the needle if there is any damage or visibly exposed metal on the shaft where it connects to the handle. • Do not use the NRG Transseptal Needle after the "Use By" date indicated on the label. • The NRG Transseptal Needle is intended for use with only those devices listed in section VII "Equipment Required" • Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.• Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • Do not attempt to puncture until firm position of the active tip has been achieved against the atrial septum. • It is not recommended to exceed five (5) radiofrequency power applications per NRG Transseptal Needle. • Do not bend the NRG Transseptal Needle. Excessive bending or kinking of the needle shaft may damage the integrity of the needle and may cause patient injury. Care must be taken when handling the needle. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the needle and DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the tip of the needle against the atrial septum. Only increase the power if low power output persists. • Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the Baylis Medical Radiofrequency Puncture System. • Ensure the distal tip is protruding the dilator/sheath assembly when visualizing on electroanatomic mapping systems. Visualization of the distal tip of the NRG Transseptal Needle may be lost when retracted within the dilator/sheath assembly.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

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